

(Endocoil™)

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= Abstract =

**Randomised Trial of Coil (Endocoil™ Stent Versus Plastic Stent
in Malignant Biliary Tract Obstruction****Don Haeng Lee, M.D., Si Young Song, M.D., Jae Bock Chung, M.D.
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Background/Aims: Endoscopic stent placement has become accepted palliative therapy for malignant biliary tract obstruction (MBTO). The main problem of plastic stent are the clogging or migration. The new self expandable super-elastic metallic coil stent (Endocoil™ Instent Inc.) is claimed to allow large lumen and prolong biliary-stent patency. In a prospective randomised trial, we compared the efficacy and frequency of stent dysfunction of Endocoil™ and plastic stent (PercuflexR, Microvasive Co.). **Method:** Between Aug. 1994 and Mar. 1995, we assigned 29 patients (21 males and 8 females, mean age 63 years) with unresectable MBTO due to cancer of bile duct (17), pancreas (6) perampullary (3), gallbladder (2) and pericholedochal LN (1). Thirteen of patients underwent Endocoil™ stents (24 Fr) and other 16 patients underwent plastic stents (12 Fr) insertion via transpapillary route. Successful insertion of stents was attained all cases and no serious complication occurred. **Results:** All patients with Endocoil™ stents and 11 (68%) patients with plastic stents were relieved completely from jaundice (T. bilirubin < 3.0 mg/dl). There was no differences in decrease of bilirubin between two groups after 7 days and 30 days after stents insertion. Median patency of the stents was significantly prolonged in patients with Endocoil™ stents compared with those with plastic stents

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* 1 .

(205 days vs 92 days). The stent dysfunction was noted 2 cases (15%) in Endocoil™ due to tumor ingrowth. In contrast, stent dysfunction was occurred in 10 cases (62%) of plastic stents due to clogging (7 cases) and migration (3 cases). The patients' overall median survival was not different significantly between two groups (Endocoil™ 250 days vs plastic 196 days). **Conclusions:** Both Endocoil™ and plastic stents offer effective bile drainage in MBTO. However Endocoil™ stents may be more effective for providing longer periods of drainage due to lower frequency of stent dysfunction than plastic stents. (Korean J Gastrointest Endosc 19: 235-241, 1999)

Key Words: Endocoil™ stent, Plastic stent, Comparative study, Malignant biliary tract obstruction (MBTO)

(nickel titanium)
(Endocoil™ stent, Instent)
,
(endoscopic retrograde biliary drainage,
ERBD)
가 가 가 .19)
.16)
,3192)
teflon, polyethylene
Wallstent, Gianturco-Rosch Z stent, Strecker stent .
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가 1)
가 (self expandable) 1994 8 1995 5
(wire) .
29
, 29 13
가 가 Endocoil™ ,
가 16
, 63 (36 80)
, 가 17 , 6 ,
가 ,10-16 3 , 2 1
가
.17,18)

Table 1. Clinical Characteristics of the Patients

	Endocoil (n=13)	Plastic (n=16)	p value
Age (mean, years)	62	66	NS
Sex (M/F)	10/3	11/5	NS
Diagnosis			
Bile duct cancer	7	10	
Pancreas cancer	3	3	
Periampullary cancer	2	1	
Gallbladder cancer	—	2	
Pericholedochal LN	1	—	
Initial TB (mg/dL)*	15.5±7.1	17.6±8.8	NS

*Mean ±SD; NS, not significant statistically; LN, lymph node; TB, total bilirubin

(Table 1).

2)

(1) **Endocoil™** : Endocoil™

(Instent Co.)

(delivery catheter)

,

12 Fr

(releasing handle)

24 Fr

Fr 7, 5 cm, 6 cm, 7 cm

, 8 1 .

Endocoil™

(ERCP)

Soehendra dilator

de-wire

guidewire

(2)

ERCP

X-

(3)

: Endocoil™

, 7 , 30

3 mg/dL

(4)

2

1

24

ERCP

(5)

t-test

chi-square test

test

(EST)

12 Fr

gui-

가

EST

12 Fr

Amsterdam

polyethylene (PercuflexR Microvasive Co.)

가

가

7 30

가:

1

,

. 1996 8

Kaplan-Meier

Log-Rank

1) 2

1 2

ERCP debris가

irrigation

3.0 mg/dL

13 가 ,

16 11 (68%) 가

Table 2. Efficacy for Relief of Jaundice

	Endocoil (n=13)	Plastic (n=16)	p value
Relief of jaundice (TB < 3.0 mg/dL)	13 (100%)	11 (68%)	0.24
Bilirubin decrease (mg/dL)*			
7 days after insertion	9.0 ± 3.0	8.7 ± 5.1	0.85
30 days after insertion	13.9 ± 7.3	11.7 ± 6.9	0.45

*Mean ± SD; TB, total bilirubin

Table 3. Causes of Stent Dysfunction

Causes	Endocoil (n=13)	Plastic (n=16)	p value
Stent dysfuction	2 (15%)	10 (62%)	0.07
Blockage	—	5	
Migration	—	2	
Tumor ingrowth	2	—	
Days of stent patency*	205 ± 82	92 ± 44	0.003

*Mean ± SD; Follow up duration : 1 13 months

(p=0.09).

7 30

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9.0, 13.9 mg/dL ,

8.7, 11.7 mg/dL

(Table 2).

2)

13 2 (15%)

Endocoil™

16 10 (62%)

clogging 7

, migration 3

가 (p=0.07)(Table 3).

205

92

(p < 0.05)(Fig. 1).

3)

13 6 , 4

, 7



Fig. 1. Cummulative patency of EndocoilR and plastic stents.

Coil™ stent)

10 , 5

6 가 ,

250 , 196

가 가

가 가

(endoscopic retrograde biliary drainage, ERBD) .20)

가 29

,16) 12 Fr 16 11
(68%) 13

가 3.0 mg/dL

.79)

가

7 30

teflon, polyethylene

Wall stent, Gianturco-Rosch Z stent, Strecker stent

3 5
30 50% (clogging)

가

(clogging)

,279)

.79)

가 , Speer 8) 10 Fr

가 8 Fr

가 가 (self expandable)
(wire)

10, 12, 15 Fr

가 12
Fr polyethylene 16 10 (62%)

, , 7

가 가 가 92 2) 12 Fr

18

143

33%

, 가 가 ,

.10-16)

, Goldin 19) 9

Instent

(Endo-

1

12
5 2 가
2 , 4 , 4.5 ,
4 , 가
3) 5
1
1 가
4 6 .
13
3.0 mg/dL
 ,
 , 1994
2 8 1995 5
가 .
205 29 (13) (16)
92 .
1) (17), (6
) , (3), (2)
 , Smits (1) 21 8
2) 63 (36 80) 가
20 71%
8 3 , 5 2) 18 mm
12 Fr Amsterdam
 , 2
1 2
3)
ERCP
debris가 irrigation
3)
3.0 mg/dL
16 11 (68%) 3.0 mg/dL
7 30
4) 13 2 (15%)
16 10 (62%)
가
가 (p=0.07).
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